National Institutes of Health
U.S. Public Health Service
Bethesda, Maryland 20892

To: [Name], Genomic Program Administrator, [NIH IC]

From: [Name], Scientific Director, [NIH IC]

Subject: Certification of [NIH IC] to Accompany Submission of the Dataset for [name of study] to an NIH-designated data repository

The submission of data to the NIH dbGaP data repository is being made with institutional approval from [NAME OF SUBMITTING INSTITUTION], along with appropriate institutional approvals from collaborating sites, as listed here:[1]

[List collaborating sites]

[NIH IC] hereby assures that submission of data from [name of principal investigator] for the study entitled [name of study] to an NIH-designated data repository meets the following expectations, as defined in the Genomic Data Sharing Policy:

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.[2]
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.[3]

  The use of aggregate-level data for general research use is not inconsistent with informed consent.[4] ☐Yes ☐No

  The display of variant ☐ alleles and/or ☐ frequencies, from this study in public variation archives (i.e., dbSNP and dbVar)[5] is not inconsistent with informed consent. ☐Yes ☐No

- The identities of research participants will not be disclosed to NIH-designated data repositories.

- [Name of the applicable Institutional Review Board (IRB)] has reviewed the investigator's proposal for data submission and assures that:
  - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.[6]

[1] Certification must be provided for all sites contributing samples. The primary site may submit *one* Institutional Certification indicating that they are providing certification on behalf of all collaborating site. Alternatively, each site providing samples may provide their own Institutional Certification.

[2] For the submission of data derived from cell lines or clinical specimens lacking research consent that were created or collected before the effective date of this Policy, the Institutional Certification needs to address only this item.

[3] For guidance on drafting data use limitations, see NIH Points to Consider in Drafting Effective Data Use Limitation Statements, http://gwas.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf

[4] Aggregate-level data include summary statistics from the research study, such as allele frequencies or effect sizes and p-values for test of association. If "yes" is checked, your aggregate-level data will be included in the Compilation of Aggregate Genomic Data, a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request.

[5] The Single Nucleotide Polymorphism Database (dbSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Varian (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: http://www.ncbi.nlm.nih.gov/SNP/ and http://www.ncbi.nlm.nih.gov/dbvar/.

[6] 45 CFR Part 46. Protection of Human Subjects. See http://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/xml/CFR-2011-title45-vol1-part46.xmL

- Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;[7]
- Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
- To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
- The investigator's plan for de-identifying datasets is consistent with the standards outlined in this Policy (see section IV.C.1.).

The data are to be made available through ☐unrestricted[8] or ☐controlled-access[9]

We hereby assure that submission of these data to dbGaP is consistent with the above statements and meets the expectations as defined in the NIH GDS Policy.

Principal Investigator
Name_____
Signature_____
Date_____

IRB Chair/Designee
Name_____
Signature_____
Date_____

Scientific Director/Designee (Signing Official)
Name_____
Signature_____
Date_____

[7] As noted earlier, for studies using data or specimens collected before the effective date of this Policy, the IRB, privacy board, or equivalent body should review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.

[8] Data made publicly available to anyone

[9] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

For guidance on drafting data use limitations, please refer to the NIH Points to Consider in Drafting Effective Data Use Limitation Statements found at: http://gds.nih.gov/pdf/nih_ptc_in_drafting_dul_statements.pdf.

Consent Group Title Options (select one of the four categories below)	**Data Use Limitations**
General Research Use (select any that apply) IRB approval required	**Use of the data is limited only by the terms of the Data Use Certification.** Requestor must provide documentation of local IRB approval.
Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only	Use of the data is limited to not-for-profit organizations.
Health/Medical/Biomedical (select any that apply) IRB approval required	**Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.** Requestor must provide documentation of local IRB approval.
Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only	Use of the data is limited to not-for-profit organizations.
Methods	Use of the data includes methods development research (e.g., development of software or algorithms)
Genetic studies only	Use of the data is limited to genetic studies only.
Disease-specific [list disease] (select any that apply) IRB approval required	**Use of the data must be related to the specified disease.** Requestor must provide documentation of local IRB approval.
Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only	Use of the data is limited to not-for-profit organizations.
Methods	Use of the data includes methods development research (e.g., development of software or algorithms)
Related disorders	Use of the data is limited to genetic studies of the specified disease and related conditions, such as _____.
Genetic studies only	Use of the data is limited to genetic studies only.
Other	[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Using the table above, please indicate in the table below the consent group(s) for each collaborating study site

Collaborating Site Name	**Study Name**	**Consent Group Title**
Ex. University of Wisconsin	*Cold Cohort Study*	*Health/Medical/Biomedical*
University of Wisconsin	*Cold Cohort Study*	*Disease-specific [Lung Cancer] Research* • *IRB approval* • *Methods*